REMARKS

Interview Summary

Applicants wish to gratefully acknowledge Examiner Johannsen's taking the time to discuss pending claim 48 in an interview with Applicant's representative, Dr. Pamela Gao, on May 18, 2004. In the interview, Dr. Gao discussed a proposed amendment to the claim and the Examiner suggested the "RNA equivalent" language. This suggested language has been incorporated in the currently amended claim.

Amendments

Claims 48, 49, 52 and 54-58 were pending following the Advisory Action dated February 12, 2004.

Applicants have deleted the protein sequences corresponding to SEQ ID NOs: 55, 58 and 62 from the sequence listing. In accordance with 37 C.F.R. § 1.825, a substitute paper copy and a computer readable format of the sequence listing are included herewith.

Applicants have cancelled Claim 49 and Claim 54.

Applicants have amended Claim 48 by adding the term "human." Thus, the amended claim is directed to the use of the method with a human patient. This amendment is supported throughout the application, e.g., page 60, line 17. Applicants have also deleted the term "at least 95%" and amended with the term an "RNA equivalent." This amendment is supported in the specification at e.g. page 41, line 26 to page 42, line 2.

Applicants have added new Claims 59-65. The subject matter of these claims is supported by the specification at e.g., page 43, line 24-30.

Applicants have added new Claim 66-69. Support for the subject matter of these claims, which includes detection "an expression product of a gene," is found throughout the specification (see, e.g., page 41, lines 26-31)

No new matter is added in any of the above amendments. The Examiner is requested to enter the amendments and reconsider the application.

Response to Advisory Action Dated February 12, 2004

Item 1

The Examiner rejected Claim 48 under 35 U.S.C.§ 112 ¶ 2 based on the recitation of "mRNA" when the SEQ ID NO:23 corresponded to a disclosed DNA sequence. Applicants have amended Claim 48 with the "RNA equivalent" language suggested by the Examiner, and which is supported by the specification. Applicants have also incorporated this language in new Claims 59 and 66. Applicants believe that the claims are definite and unambiguous and respectfully assert that they are in a form allowable under 35 U.S.C.§ 112 ¶ 2.

Item 2

The Examiner has maintained a new matter rejection with respect to Applicants' Preliminary Amendment filed October 16, 2001, because the sequences and corresponding SEQ ID NOs: 54-62 were added to the application without any declaratory evidence that these sequences corresponded to the accession numbers originally disclosed in Figure 10 at the time the application was filed.

In response, Applicants submits herewith a Declaration pursuant to 37 C.F.R. §1.132 by Dr. Daniel E. H. Afar attesting that to his knowledge SEQ ID Nos: 54, 56-57, and 59-61 submitted in the Preliminary Amendment dated October 16, 2001 correspond to the Gene Bank accession numbers in Figure 10 at the time the application was filed (see attached Declaration Pursuant to 37 C.F.R. §1.132)

With respect to protein sequences corresponding to SEQ ID Nos: 55, 58, and 62, Applicants submit a new Sequence Listing that deletes these sequences. In accordance with 37 C.F.R. § 1.825, a substitute paper copy and a computer readable format of the sequence listing are included herewith.

Item 3

The Examiner refused to consider the references cited in the Information Disclosure Statement ("IDS") submitted by Applicants on December 12, 2003 for allegedly failing to comply with 37C.F.R. § 1.97(d) because a statement as specified in 37 C.F.R. § 1.97(e)(1) was not included. However, the requisite statement was, in fact, included when the IDS was

submitted. A copy of the Statement is enclosed, and Applicants respectfully request that the Examiner consider the references cited in that IDS

CONCLUSION

Applicants believe that this RCE application is in good and proper condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 463-8133.

Respectfully submitted,

Date: July 1, 2004

Adam K. Whiting (Reg. No. 44,400)
David Clough (Reg. No. 36,107)

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:
David Mark *et al.*
Application No. 09/525,361
Filed: March 15, 2000

Art Unit: 1634
Examiner: Johannsen, D.
Attorney's Docket No:
05882.0129.CPUS03

For: **NOVEL METHODS FOR DIAGNOSING BREAST CANCER, COMPOSITIONS AND METHODS OF SCREENING FOR BREAST CANCER MODULATORS**

DECLARATION PURSUANT TO 37 C.F.R. §1.132

Sir:

I, Daniel E. H. Afar, do hereby declare as follows:

1. I am an Associate Director of Research Project Management currently working at Protein Design Labs, Inc. I received my Ph.D. Department of Biochemistry, University of Ottawa, Ottawa, Ont., Canada. I have 20 years of research experience in molecular biology and cancer research. My Curriculum Vitae is attached as Appendix A.

2. I have reviewed and am familiar with the particular accession numbers disclosed in Figure 10 of the present application. I have reviewed and am familiar with the polynucleotide sequences of SEQ ID Nos: 54, 56, 57, 59, 60 and 61. To the best of my knowledge, on March 15, 2000, the GenBank entries corresponding to accession numbers U41060, R46025, Z29083, AA428062, AA256485, and M57230, disclosed the polynucleotide sequences of SEQ ID Nos: 54, 56, 57, 59, 60 and 61, respectively.

3. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that the making of willful false statements

and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity of the applications or any patent issuing thereon.

Respectfully submitted,

Dated: June 29, 2004

Daniel E. H. Afar,Ph.D
Protein Design Labs, Inc.

Appendix A

CURRICULUM VITAE
Daniel E. H. Afar, PhD

Date of birth: December 18th, 1961.

Place of birth: Frankfurt\Main, Germany.

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Work Experience:

4/2003-present Associate Director, Research Project Management
Protein Design Labs, Inc., Fremont, CA, USA

9/2000-4/2003 Senior Scientist, Genomics and Project Management
Eos Biotechnology, South San Francisco, CA, USA

5/1997- 8/2000 Research Scientist, Gene Discovery
UroGenesys Inc., Santa Monica, CA, USA

Education:

1992-1997 Postdoctoral Fellow, Howard Hughes Medical Institute, UCLA, Los Angeles, CA, USA.

1987-1992 Ph.D. Department of Biochemistry, University of Ottawa, Ottawa, Ont., Canada.

1984-1987 M.Sc. Department of Pharmacology, McGill University, Montreal, Que., Canada.

1981-1984 Honours B.Sc. Department of Biology, McGill University, Montreal, Que., Canada.

Awards:

1995-1997 Leukemia Society of America, Special Fellowship.
1992-1995 Medical Research Council of Canada, Postdoctoral Fellowship.
1989-1991 Studentship, University of Ottawa, Canada.
1985-1990 FRSQ Studentship, Province of Quebec, Canada.
1984-1985 FCAC Studentship, Province of Quebec, Canada.

Publications:

1. Beauchemin, N., Turbide, C., **Afar, D.**, Bell, J., Raymond, M., Stanners, C. P., and Fuks, A. A mouse analogue of the human carcinoembryonic antigen. Cancer Res, *49:* 2017-2021, 1989.

2. Salzer, J. L., Pedraza, L., Brown, M., Struyk, A., **Afar, D.**, and Bell, J. Structure and function of the myelin-associated glycoproteins. Ann N Y Acad Sci, *605:* 302-312, 1990.

3. **Afar, D.** E., Salzer, J. L., Roder, J., Braun, P. E., and Bell, J. C. Differential phosphorylation of myelin-associated glycoprotein isoforms in cell culture. J Neurochem, *55:* 1418-1426, 1990.

4. **Afar, D. E.,** Marius, R. M., Salzer, J. L., Stanners, C. P., Braun, P. E., and Bell, J. C. Cell adhesion properties of myelin-associated glycoprotein in L cell fibroblasts. J Neurosci Res, *29:* 429-436, 1991.

5. Icely, P. L., Gros, P., Bergeron, J. J., Devault, A., **Afar, D. E.**, and Bell, J. C. TIK, a novel serine/threonine kinase, is recognized by antibodies directed against phosphotyrosine. J Biol Chem, *266:* 16073-16077, 1991.

6. Howell, B. W., **Afar, D. E.**, Lew, J., Douville, E. M., Icely, P. L., Gray, D. A., and Bell, J. C. STY, a tyrosine-phosphorylating enzyme with sequence homology to serine/threonine kinases. Mol Cell Biol, *11:* 568-572, 1991.

7. **Afar, D. E.**, Stanners, C. P., and Bell, J. C. Tyrosine phosphorylation of biliary glycoprotein, a cell adhesion molecule related to carcinoembryonic antigen. Biochim Biophys Acta, *1134:* 46-52, 1992.

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9. Lach, B., Rippstein, P., Atack, D., **Afar, D. E.**, and Gregor, A. Immunoelectron microscopic localization of monoclonal IgM antibodies in gammopathy associated with peripheral demyelinative neuropathy. Acta Neuropathol (Berl), *85:* 298-307, 1993.

10. Almazan, G., **Afar, D. E.**, and Bell, J. C. Phosphorylation and disruption of intermediate filament proteins in oligodendrocyte precursor cultures treated with calyculin A. J Neurosci Res, *36:* 163-172, 1993.

11. **Afar, D. E.**, Goga, A., Cohen, L., Sawyers, C. L., McLaughlin, J., Mohr, R. N., and Witte, O. N. Genetic approaches to defining signaling by the CML-associated tyrosine kinase BCR-ABL. Cold Spring Harb Symp Quant Biol, *59:* 589-594, 1994.

12. **Afar, D. E.**, Goga, A., McLaughlin, J., Witte, O. N., and Sawyers, C. L. Differential complementation of Bcr-Abl point mutants with c-Myc. Science, *264:* 424-426, 1994.

13. Cohen, L., Mohr, R., Chen, Y. Y., Huang, M., Kato, R., Dorin, D., Tamanoi, F., Goga, A., **Afar, D.**, Rosenberg, N., and et al. Transcriptional activation of a ras-like gene (kir) by oncogenic tyrosine kinases. Proc Natl Acad Sci U S A, *91:* 12448-12452, 1994.

14. Saffran, D. C., Parolini, O., Fitch-Hilgenberg, M. E., Rawlings, D. J., **Afar, D. E.**, Witte, O. N., and Conley, M. E. Brief report: a point mutation in the SH2 domain of Bruton's tyrosine kinase in atypical X-linked agammaglobulinemia. N Engl J Med, *330:* 1488-1491, 1994.

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Presentations:

(1) **XIX Seattle/San Diego Meeting**. Seattle, Washington. Oct. 22-24, 1993 (oral presentation).

(2) **Keystone Symposium on Molecular Basis of Cancer Therapy**. Tamarron, Colorado. March 4-10, 1994 (invited speaker).

(3) **Neva-Wilsede Meeting III: Modern trends in human leukemia IX.** Wilsede, Germany, June 19-21. St.Petersburg, Russia, June 22-26, 1994 (invited speaker).

(4) **Banbury Center Conference on Targets for Specific Therapies in Leukemia.** Cold Spring Harbour Laboratory, New York, Sept. 11-14, 1994 (invited speaker).

(5) **XX Salk/Seattle Meeting.** San Diego, CA, Nov. 11-12, 1994 (oral presentation).

(6) **Gordon Research Conference- The Molecular and Genetic Basis of Cell Proliferation.** Meriden, NH, July 9-14, 1995 (invited speaker).

(7) **International Conference on Chronic Myelocytic Leukemia- Biology and Treatment.** Jerusalem, Israel, Jan 28-31, 1996 (invited speaker).

(8) **Tyrosine phosphorylation and Cell Signaling- The Salk Institute.** San Diego, CA, Aug. 21-25, 1996 (oral presentation).

(9) **AACR 91st Annual Meeting,** San Francisco, CA, April 1-5, 2000 (oral presentation).

(10) **Mouse Models of Human Cancers Consortium and Prostate SPOREs Meeting.** Bethesda, MD, Nov. 21-22, 2002 (invited speaker).

Patents:

Issued US Patents - US Patent Number/Date Issued/Title

1. US6329503; Dec. 11, 2001: Serpentine transmembrane antigens expressed in human cancers and uses thereof.

2. US6277972; Aug. 21, 2001: BPC-1: a secreted brain specific protein expressed and secreted by prostate and bladder cancer cells.

3. US6509458; Jan. 21, 2003: Gene expressed in prostate cancer.

4. US6566078; May 20, 2003: Secreted protein called 36P6D5 characteristic of tumors.

5. US6602501; Aug. 5, 2003: C-type lectin transmembrane antigen expressed in human prostate cancer and uses thereof.

6. US6652859; Nov. 25, 2003: PTANS: testis specific proteins expressed in prostate cancer.

PCT Publication Number/Date Published/Title

1. WO9958560A2; Nov. 18, 1999: PROSTAPIN GENE AND PROTEIN AND USES THEREOF.

2. WO9962941A2; Dec. 9, 1999: NOVEL SERPENTINE TRANSMEMBRANE ANTIGENS EXPRESSED IN HUMAN CANCERS AND USES THEREOF.

3. WO9962942A2; Dec. 9, 1999: NOVEL TUMOR ANTIGEN USEFUL IN DIAGNOSIS AND THERAPY OF PROSTATE AND COLON CANCER.

4. WO009691A2; Feb. 24, 2000: BPC-1: A SECRETED BRAIN SPECIFIC PROTEIN EXPRESSED AND SECRETED BY PROSTATE AND BLADDER CANCER CELLS.

5. WO0012709A2; March 9, 2000: PHELIX: A TESTIS-SPECIFIC PROTEIN EXPRESSED IN CANCER.

6. WO0020589A2; April 13, 2000: PTANs: TESTIS SPECIFIC PROTEINS EXPRESSED IN PROSTATE CANCER.

7. WO0020638A2; April 13, 2000: METHODS AND COMPOSITIONS FOR THE DIAGNOSIS AND THERAPY OF PROSTATE CANCER.

8. WO0018925; April 6, 2000: GENE EXPRESSED IN PROSTATE CANCER.

9. WO0020584; April 13, 2000: HUMAN GENE EXPRESSED IN CANCERS OF PROSTATE, BLADDER, PANCREAS AND COLON, 36P1A6.

10. WO0061610; Oct. 19, 2000: NOVEL PROSTATE-RESTRICTED GENE EXPRESSED IN PROSTATE CANCER.

11. WO0061746; Oct. 19, 2000: 13 TRANSMEMBRANE PROTEIN EXPRESSED IN PROSTATE CANCER.

12. WO0112811; Feb. 22, 2001: C-TYPE LECTIN TRANSMEMBRANE ANTIGEN EXPRESSED IN HUMAN PROSTATE CANCER AND USES THEREOF.

13. WO0125434; Apr. 12, 2001: G PROTEIN-COUPLED RECEPTOR UP-REGULATED IN PROSTATE CANCER AND USES THEREOF.

14. WO0131012; May 3, 2001: GENE UPREGULATED IN CANCERS OF THE PROSTATE.

15. WO0131015; May 3, 2001: 36P6D5: SECRETED TUMOR ANTIGEN.

16. WO0131343; May 3, 2001: DIAGNOSIS AND THERAPY OF CANCER USING SGP28-RELATED MOLECULES.

17. WO0155391; Aug. 2, 2001: 84P2A9: A PROSTATE AND TESTIS SPECIFIC PROTEIN HIGHLY EXPRESSED IN PROSTATE CANCER.

18. WO0159110; Aug. 16, 2001: 34P3D7: A TISSUE SPECIFIC PROTEIN HIGHLY EXPRESSED IN PROSTATE CANCER.

19. WO0159115; Aug. 16, 2001: 83P5G4: A TISSUE SPECIFIC PROTEIN HIGHLY EXPRESSED IN PROSTATE CANCER.

20. WO0162925; Aug. 30, 2001: 103P2D6: TISSUE SPECIFIC PROTEIN HIGHLY EXPRESSED IN VARIOUS CANCERS.

21. WO0179557; Oct. 25, 2001: GTP-BINDING PROTEIN USEFUL IN TREATMENT AND DETECTION OF CANCER.

22. WO0190157; Nov. 29, 2001: 98P7C3: HOMEODOMAIN PROTEIN HIGHLY EXPRESSED IN VARIOUS CANCERS.

23. WO0196391; Dec. 20, 2001: 55P4H4: GENE EXPRESSED IN VARIOUS CANCERS.

24. WO0214361; Feb. 21, 2002: NUCLEIC ACIDS AND CORRESPONDING PROTEINS ENTITLED 83P2H3 AND CaTrF2E11 USEFUL IN TREATMENT AND DETECTION OF CANCER.

25. WO0216593; Feb. 28, 2002: NUCLEIC ACID AND CORRESPONDING PROTEIN NAMED 158P1D7 USEFUL IN THE TREATMENT AND DETECTION OF BLADDER AND OTHER CANCERS.

26. WO0216598; Feb. 28, 2002: NUCLEIC ACID AND CORRESPONDING PROTEIN NAMED 158P1H4 USEFUL IN THE TREATMENT AND DETECTION OF BLADDER AND OTHER CANCERS.

27. WO0218578; Mar. 7, 2002: NUCLEIC ACID AND CORRESPONDING PROTEIN ENTITLED 85P1B3 USEFUL IN TREATMENT AND DETECTION OF CANCER.

28. WO0230268; Apr. 18, 2002: METHODS OF DIAGNOSIS OF PROSTATE CANCER, COMPOSITIONS AND METHODS OF SCREENING FOR MODULATORS OF PROSTATE CANCER.

29. WO02059377; Aug. 1, 2002: METHODS OF DIAGNOSIS OF BREAST CANCER, COMPOSITIONS AND METHODS OF SCREENING FOR MODULATORS OF BREAST CANCER.

30. WO02060953; Aug. 8, 2002: NUCLEIC ACID AND ENCODED ZINC TRANSPORTER PROTEIN ENTITLED 108P5H8 USEFUL IN TREATMENT AND DETECTION OF CANCER.

31. WO02072785; Sept. 19, 2002: NUCLEIC ACID AND CORRESPONDING PROTEIN ENTITLED 125P5C8 USEFUL IN TREATMENT AND DETECTION OF CANCER.

32. WO02083068; Oct. 24, 2002: NUCLEIC ACID AND CORRESPONDING PROTEIN ENTITLED 121P2A3 USEFUL IN TREATMENT AND DETECTION OF CANCER.

33. WO02095009; Nov. 28, 2002: NUCLEIC ACID AND CORRESPONDING PROTEIN ENTITLED 121P1F1 USEFUL IN TREATMENT AND DETECTION OF CANCER.

34. WO02098358; Dec. 12, 2002: METHODS OF DIAGNOSIS AND TREATMENT OF ANDROGEN-DEPENDENT PROSTATE CANCER, PROSTATE CANCER UNDERGOING ANDROGEN-WITHDRAWAL, AND ANDROGEN-INDEPENDENT PROSTATE CANCER.

35. WO03025138; Mar. 27, 2003: METHODS OF DIAGNOSIS OF CANCER COMPOSITIONS AND METHODS OF SCREENING FOR MODULATORS OF CANCER.

36. WO03042661; May 22, 2003: METHODS OF DIAGNOSIS OF CANCER, COMPOSITIONS AND METHODS OF SCREENING FOR MODULATORS OF CANCER.

37. WO03075855; Sep. 18, 2003: ANTIBODIES AGAINST CANCER ANTIGEN TMEFF2 AND USES THEREOF.